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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,581	09/28/2001	Sung-Kwon Jung	58378.124	4006

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EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/966,581	Applicant(s) JUNG ET AL.	
	Examiner Kaj Olsen	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) 1-19 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 20-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-19, drawn to flux determining system, classified in class 204, subclass 403.01.

   II. Claims 20-35, drawn to method of determining flux, classified in class 205, subclass 777.5.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to perform static electrode experiments or for potentiometry.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Emily Whelan on 9-15-2003 a provisional election was made without traverse to prosecute the invention of group II, claims 20-35. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-19 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. In claim 34, it is unclear how to interpret the phrase "the viability of an embryo". What would one possessing ordinary skill in the art reasonably construe as being a viable embryo? Clarification is requested.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 20, 21, 23, 24, 27-33, and 35 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Jung et al (Anal. Chem. 2001, 73, pp. 3759-3767). The American Chemical Society indicates that this article was published on-line on 6/30/2001 and thereby qualifies as prior art under 35 U.S.C. 102(a).

11. The subject matter of Jung substantially overlaps the subject matter of the present invention (e.g. fig. 1-7 of Jung appear to be almost identical to fig. 1-7 of the present invention).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jung in view of Pritchard et al (USP 5,762,770).

15. Jung set forth all the limitations of the claim, but did not explicitly recite the use of either dehydrogenase or of lactate oxidase. Pritchard teaches in an alternate biosensor that glucose dehydrogenase can also be utilized for the detection glucose (see table 1). Table 1 also shows that a given biosensor can be modified to measure other analytes such as lactose using lactate oxidase. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the dehydrogenase teaching of Pritchard for the method of Jung because the substitution of one known enzyme for another known enzyme requires only routine skill in the art. In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the lactose teaching of Pritchard for the method of Jung in order to extend the utility of the flux sensor to other art recognized bioanalytes.

16. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jung in view of Spring et al (USP 5,643,721).

17. Jung set forth all the limitations of the claim, but did not explicitly recite the use of glutamate oxidase as the enzyme. Spring teaches in an alternate biosensor that sensors suitable for monitoring glucose can also be modified to sense glutamate by use of glutamate oxidase (see example 7 starting at col. 23). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Spring for the method of Jung in order to extend the utility of the flux sensor to other art recognized bioanalytes.

18. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jung in view of Keefe et al (USP 6,062,225).

19. Jung set forth all the limitations of the claim (see rejection above), but did not explicitly recite the use of the sensor for the determination of embryo viability (see 112 rejection above).

Keefe discloses that analyte flux measurements may be utilized to determine if the embryos are morphologically capable of cleavage (col. 1, line 52 through col. 2, line 19). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Keefe for the method of Jung in order to assist a medical practitioner in determining the relative health of a developing fetus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number form after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

Kaj K. Olsen
Patent Examiner
AU 1753
September 22, 2003